REMARKS

Claims 1-49 are pending in the application with claims 22-35 currently under examination. Claims 1-21 and 36-49 have been withdrawn from consideration as being directed to a non-elected invention. Applicant has reviewed the rejections set forth in the pending Office Action, and respectfully traverse all grounds for the reasons that follow.

Rejections Under 35 U.S.C. § 101

Claims 24-35 stand rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter allegedly because they either lack a physical transformation outside the computer and lack a practical application. In particular, the Office alleges that the claims are directed to determining a multidimensional coordinate point representing a data element of a physically perturbed biochemical system where the physical perturbation can occur before the determination step. The Office concludes that the claimed step is not a physical act performed outside a computer or a measuring of physical objects or activities the two safe harbor categories satisfying the physical transformation requirement for statutory subject matter is not satisfied.

The Board of Appeals and Interferences of the U.S. Patent and Trademark Office has now overturned rejections attempting to require method claims to include machine or computer processing limitations such as the instant requirement for a physical transformation or an interaction with a computer. *In re Lundgren*, B.P.A.I. Case Nos. 2003-2088 (Sept. 28, 2005) (*Per Curium*). This decision by the U.S.P.T.O. itself establishes a new precedent invalidating Examiners' rejections which allege nonstatutory subject matter because the claims lack a physical transformation outside a computer or do not require machine implementation. In light of *In re Lundgren*, withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 22-35 under 35 U.S.C. § 102(b) stand rejected as anticipated by Stoughton et al. allegedly because Stoughton et al. describe comparing microarray profiles that measure relative changes of mRNA and graded drug exposure. The Office cites to certain passages in Stoughton et al. and appears to allege that positional addressable transcript microarrays and making measurements involving locations containing x and y dimensions constitute a multidimensional

coordinate point. Office Action at page 6, para. 2, and page 8, para. 2. The Office further alleges that Applicants' claimed multidimensional coordinate point fails to recite a combination of multiple values into a multidimensional coordinate point.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). The Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention. Staughton et al. fails to anticipate the claimed invention because Staughton et al. does not describe a multidimensional coordinate point and described and claimed in the application.

The claims are directed to determining a multidimensional coordinate point representing a data element of one or more components of a perturbed biochemical system. The multidimensional coordinate point is claimed as including n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system. In contrast, Staughton et al. appear to merely describe the production and measurement of samples in a microarray. In this regard, Staughton et al. fails to describe a point that includes n parameters. Thus, Staughton et al. fail to describe a multidimensional coordinate point as is claimed by the invention.

Applicants have claimed a "multidimensional coordinate point." Applicants have specifically defined the meaning of this term and are permitted to be their own lexicographer. See, for example, M.P.E.P. § 2111.01. Applicants have neither imported limitations into the claims nor have Applicants argued limitations not included in the claims. Further, the Federal Circuit has directed the courts that when "[p]roperly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (*en banc*). The Federal Circuit has reaffirmed this opinion very recently where the Court found error in emphasizing the ordinary meaning of the term "'adjustable' without adequate grounding of that tem within the context of the specification," which described adjustment as taking place without removing a head unit rather

than generally being capable of being change. *Curtiss Wright Flow Control Corp. v. Velan, Inc.*, Case No. 05-1373, slip op. at 7 (Fed. Cir. February 15, 2006).

Therefore, the meaning of the term "multidimensional coordinate point" should be accorded its meaning as it is defined in, and in view of the entire application. Applicants have set forth this meaning and have shown its distinctions over Staughton et al. in their previous responses.

The application teaches that a "multidimensional coordinate point" refers to:

> [A] coordinate defined by "n" parameters, where n is the number of components in a biochemical system, or subset thereof, and each parameter is a data element of a component of the biochemical system, or subset thereof. Therefore, a multidimensional coordinate point representative of a data element of two components is defined by two parameters corresponding to values representative of data elements of the two components. Similarly, a multidimensional coordinate point representative of data elements of three molecules is defined by three parameters corresponding to values representative of the data elements of the three components (see Figure 1). A multidimensional coordinate point representative of the data elements of n components is defined by n parameters corresponding to the values of the data elements of n components. Therefore, multidimensional coordinate points for a group of components such as the components of a pathway, network or biochemical system is found in n-dimensional shape space. As such, the term "multidimensional shape space" is intended to mean a set of multidimensional coordinate points for a group of components of a pathway, network or biochemical system.

Application at page 17, line 25 through page 18, line 19 (emphasis added).

Therefore, the application defines a "multidimensional coordinate point" as a coordinate which is defined by "n" parameters. Further, and as described above and in Applicants' previous responses, the claims specifically recite n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system. Such a multidimensional coordinate point is distinct from the descriptions in Staughton et al.

The Office alleges that column 45, lines 17-39; column 46, lines 58-67; column 51, lines 39-49, and column 52, lines 1-17, describe the claimed multidimensional coordinate point. Applicants respectfully disagree. Column 45, lines 17-39 read:

> In one embodiment, transcript arrays are produced by hybridizing detectably labeled polynucleotides representing the mRNA transcripts present in a cell (e.g., fluorescently labeled cDNA synthesized from total cell mRNA) to a microarray. A microarray is a surface with an ordered array of binding (e.g., hybridization) sites for products of many of the genes in the genome of a cell or organism, preferably most or almost all of the genes. Microarrays can be made in a number of ways, of which several are described below. However produced, microarrays share certain characteristics: The arrays are reproducible, allowing multiple copies of a given array to be produced and easily compared with each other. Preferably the microarrays are small, usually smaller than 5 cm.sup.2, and they are made from materials that are stable under binding (e.g. nucleic acid hybridization) conditions. A given binding site or unique set of binding sites in the microarray will specifically bind the product of a single gene in the cell. Although there may be more than one physical binding site (hereinafter "site") per specific mRNA, for the sake of clarity the discussion below will assume that there is a single site. In a specific embodiment, positionally addressable arrays containing affixed nucleic acids of known sequence at each location are used.

Id. (emphasis added).

As shown in the underlined text, this passage is directed to the production of arrays or microarrays. In one embodiment the analyte nucleic acids can be of known sequence at a known position within an array. However, this passage is silent as to determining a multidimensional coordinate point where the coordinate point includes n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system. Rather, in the passage above, Staughton et al. merely describe the production of arrays where nucleic acid analytes are produced at different locations within the array.

The cited passage in Staughton et al. at column 46, lines 58-67, reads:

> Microarrays are known in the art and consist of a surface to which probes that correspond in sequence to gene products (e.g., cDNAs, mRNAs, cRNAs, polypeptides, and fragments thereof), can be specifically hybridized or bound at a known position. In one embodiment, the microarray is an array (i.e., a matrix) in which each position represents a discrete binding site for a product encoded by a gene (e.g., a protein or RNA), and in which binding sites are present for products of most or almost all of the genes in the organism's genome.

Id. (emphasis added).

As with the previous passage, the underlined text in this passage also is directed to microarrays wherein a nucleic acid analyte can be located at a known position within the array.

Similarly, this passage also is silent as to determining a multidimensional coordinate point where the coordinate point includes n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system.

The cited passage in Staughton et al. at column 51, lines 39-49, reads:

> In one embodiment of the invention, transcript arrays reflecting the transcriptional state of a cell of interest are made by hybridizing a mixture of two differently labeled probes each corresponding (i.e., complementary) to the mRNA of a different cell of interest, to the microarray. According to the present invention, the two cells are of the same type, i.e., of the same species and strain, but may differ genetically at a small number (e.g., one, two, three, or five, preferably one) of loci. Alternatively, they are isogeneic and differ in their environmental history (e.g., exposed to a drug versus not exposed).

Id. (emphasis added).

As shown by the underlined text, Staughton et al. describe in this passage the hybridization of a mixture of labeled probes to the microarray. Hence, if there are complementary nucleic acids at a particular location within the microarray, the probes can detect the analyte. As with the previous passages, there is nothing in this description directed to determining a multidimensional coordinate point where the coordinate point includes n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system. Rather, Staughton et al. merely describe assaying an array with a probe mixture.

The cited passage in Staughton et al. at column 52, lines 1-17, reads:

> In certain embodiments of this invention, it is advantageous to make measurements of graded drug exposure and of graded levels of the modification/perturbation control parameters. This is advantageous in the case of the continuous interpretation of the logical operators of the network model previously described in Section 5.1. It is also advantageous where graded exposures and modifications are used to clearly identify saturating levels. In this case, the density of levels of the graded drug exposure and graded perturbation control parameter is governed by the sharpness and structure in the individual gene responses--the steeper the steepest part of the response, the denser the levels needed to properly resolve the response. Preferably, six to ten levels of perturbation or exposure over a hundred-fold total range was just sufficient to

> modification/perturbation control parameters. This is advantageous in the case of the continuous interpretation of the logical operators of the network model previously described in Section 5.1. It is also advantageous where graded exposures and modifications are used to clearly identify saturating levels. In this case, the density of levels of the graded drug exposure and graded perturbation control parameter is governed by the sharpness and structure in the individual gene responses--the steeper the steepest part of the response, the denser the levels needed to properly resolve the response. Preferably, six to ten levels of perturbation or exposure over a hundred-fold total range was just sufficient to resolve the gene expression responses. However, more exposures are preferably to more finely represent this pathway.

Id. (emphasis added).

The underlined text above shows that this cited passage in Staughton et al. is directed to the amount and quality of individual gene response measurements taken from the array that are sufficient to resolve a response following a perturbation. As with the other passages set forth above, this passage also is silent as to determining a multidimensional coordinate point where the coordinate point includes n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system.

Applicants have described and claimed a method for assigning a cellular function to a component of a biochemical system. The method includes determining a multidimensional coordinate point that include n parameters, wherein n corresponds to the number of measured components within a biochemical or constituent system. Staughton et al. appear to merely describe the production and measurement of samples in a microarray. Therefore, Staughton et al. fail to describe a multidimensional coordinate point that includes n parameters. Absent such a description of a multidimensional coordinate point as claimed, Stoughton et al. cannot anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

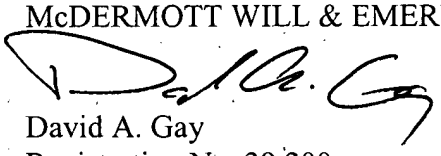
CONCLUSION

In light of the Remarks herein, Applicants submit that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



David A. Gay
Registration No. 39,200

4370 La Jolla Village Drive, Suite 700
San Diego, CA 92122
Phone: 858.535.9001 DAG:MWE
Facsimile: 858.597.1585
Date: June 9, 2006

Please recognize our Customer No. 41552 as our correspondence address.

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